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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,759	09/18/2001	John K. Morris	MED-04703/29	8880

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EXAMINER

DEMILLE, DANTON D

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,759	MORRIS ET AL.	
	Examiner Danton DeMille	Art Unit 3764	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>13 January 2003</u> .			
2a) <input checked="" type="checkbox"/> This action is FINAL . 2b) <input type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>21-50</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>21-50</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		6) <input type="checkbox"/> Other: _____.	

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claims 21-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6290662.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to leave out the details of the pressure sensor and program the electrical circuitry to perform any desired method of therapy desired. Claim 21 is broader than those of the patent and therefore is anticipated by the patent claims. Every limitation in claim 21 has already been recited in the patent claims. There is no unobviousness to leave out limitations so as to not be so limited. If a claimed invention in the application is obvious over a claimed invention in the patent, there would be an unjustified extension of the patent and an obvious-type double patenting rejection is proper. See MPEP 804.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 21-28, 32-34 and 37-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri '458.** Taheri teaches a flexible fabric outer shell, an inflatable/deflatable bladder supported between the inner wall of the outer shell and the human limb and column 4, lines 49-53, teach "the compressor 66 is a small portable battery operated pump, and the electronics 70, 71 and 72 consist of a microcircuit which has very small volume and weight. The foregoing features thus enhance the portability of the device." Clearly Taheri teaches all of the structure recited but appears silent with regard to whether or not the fabric outer shell is inelastic or not. Clearly the fabric outer shell would have to be inelastic in order to provide the function recited in column 3, lines 35-38, "when the bladders are inflated, they will bulge inwardly toward the adjacent soft tissue to provide good pressure against the deep veins." If the fabric were elastic then the bladders would not bulge inwardly. They would bulge outwardly loosing part of the pressure against the deep veins thereby destroying the Taheri reference. It would be inherent that the cloth fabric of the outer shell would be inelastic however, to any extent it is felt that such is not inherent it would have been obvious to one of ordinary skill in the art to modify Taheri to make it inelastic so that the bladders expand inwardly toward the adjacent soft tissue to provide good pressure against the deep veins. Regarding the dependent claims reciting different time intervals of operation, these claims merely recited details and timing of the intended use of the device. Clearly these limitations of intended use are obvious practical considerations dependent of the specific patient and desired therapy. Clearly the programmable operation of the pulse generator is capable of being programmed to perform

whatever desired time intervals desired. There is no unobviousness to find the optimum operational characteristics for a particular therapy. The only difference between the claimed invention and Taheri is the exact timing or operation of inflation of the bladders. There are no structural differences between the claims and the Taheri device.

7. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri '458 in view of Tumey et al. '801. Tumey teaches the well known convention of using pressure sensors 47 for stopping the pressure when it reaches a desired level. It would have been obvious to one of ordinary skill in the art to modify Taheri to include pressure sensors as taught by Tumey to control the pressurization of the bladders from going over the desired pressure limit.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri '458 in view of Vinmont. Vinmont teaches the convention of using the inflatable bladder system inside a cast. There is no unobviousness to the intended use of the system. Vinmont exemplifies another conventional alternative outer shell formation. It would have been obvious to one of ordinary skill in the art to modify Taheri to use it in combination with a cast as taught by Vinmont since the art of improving cardiocephalic venous flow applies to people in casts who are likewise ambulatory as well as taught by Vinmont.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri '458 in view of Corcoran. Corcoran teaches the convention of stimulating the hand as well as the foot. It would have been obvious to one of ordinary skill in the art to modify Taheri to use the device for the hand as well as the foot as taught by Corcoran for those people who need to stimulation of those limb extremities.

10. **Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri '458 in view of Johnson, Jr. et al. '262.** It would have been obvious to one of ordinary skill in the art to modify Taheri to use a rigid outer shell as taught by Johnson as obvious equivalent alternative form for the cuff.

Response to Arguments

11. Applicant's arguments filed 1/13/03 have been fully considered but they are not persuasive.

12. Regarding the double patenting issue and applicant's request for information why it would be obvious to "leave out the details", it is noted that every limitation of claim 21 is anticipated by the patent claims. Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See MPEP 804 II(B)(1). Claim 21 is claiming the very same invention as that recited in the previous patent. Clearly this is double patenting.

13. Regarding Taheri and the art of inflatable cuffs, applicant is not convinced that the use of inelastic outer shells or covering is well known to the artisan of ordinary skill. Applicant argues that the cloth fabric outer shell of Taheri could be made of elastic material and "would still bulge inwardly, though to a lesser degree". Applicant admits to the shortcomings to a cuff made with an elastic outer shell. The prior art has already figured this out. It doesn't take one of ordinary skill in the art to realize that a cuff tightly wrapped around the limb of a patient made entirely of rubber, when expanded, would primarily expand outward. The limb of the patient would offer

significantly more resistance to the expanding cuff than no resistance outwardly. The cuff would expand outwardly. This is a total waste of energy and is extremely inefficient.

14. In fact, all one has to do is look to applicant's own disclosure to find this is true. In the specification, page 2, applicant has disclosed as prior art Patent No. 4,841,956 to Gardner et al. Within this reference, Gardner teaches column 2, lines 44-48, "the panel 18 of flexible material which is the outer half of the bag may be stoutly resistive to stretch, thus providing a circumferential tie, whereby bag-inflation pressures are assuredly inward". Clearly this proves the examiner's position that it is well known to provide an outer covering or shell with inelastic material "stoutly resistive to stretch" so that inflation pressure are assuredly directed inwardly.

15. Regarding the dependent claims reciting different functional intended use operations of the device, Taheri uses a program memory 72 for controlling the inflation timing and operation. Taheri teaches the means in which to store a specific program mode of operation of the device. It is merely a matter of storing the desired program within the program memory. Such details are dependent on practical intended use considerations for each patient. Different patients require different operational parameters. That is the purpose of program memory. Computers offer the ability to control the inflation sequence of these cuffs to best suit the needs of each patient. Different ailments, different parts of the body, different pressures, different patients all require different parameters in which to best operate the inflation sequence for each individual patient. Programming the inflation sequence and pressures for any one specific patient is well within the realm of the artisan of ordinary skill. There is no unobviousness to program any one specific operational sequence or pressure requirements. The structure taught by Taheri is capable of performing the operations required and therefore comprehends the claim limitations. The only

difference between the claims and Taheri is the method of operation. It doesn't take one of ordinary skill in the art to know that different patients require different modes of operation and a device that has a program memory for storing different modes of operation would provide the needed requirements. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

16. Regarding the limitation that "the controller is operative to reduce the rate of cycling between compression and decompression as a function of time" again such details can be programmed in the Taheri device and are well within the realm of the artisan of ordinary skill. Modifying the operation of the over time to accommodate the progress of each patient is not new. Such details have already been considered by the prior art. For example, Watson et al. teaches in column 2, lines 15-17, "This allows blood flow to be customized and augmented over time for each individual patient and minimizes the time that blood is allowed to pool in the limb." Watson measures the time it takes for the venous system of each patient to refill and return to steady state. Watson provides a method to adjust the depressurization time between pulses thereby controlling the cycling between compression and decompression as a function of time. The timing is augmented over time for each individual patient as they improve and change over time. Watson exemplifies that the operation of the device can be augmented over time to accommodate each individual patient. Clearly, this proves the examiner's position that it would

have been obvious to control the timing of the pulses including changing the cycling of pulses over time as exemplified by Watson.

17. Regarding the application of Tumey, it is not clear how applicant can disregard the teaching of Tumey. Applicant argues that there is no teaching or suggestion to make the modification from the prior art. As pointed out in the rejection Tumey teaches that it is well known to use pressure sensors 47 for stopping the pressure when it reaches a desired level, column 8, lines 13-32.

18. It is also not clear how applicant can disregard the teaching of Vinmont. Applicant argues there is no support in the prior art for improving venous flow within the cast. Vinmont clearly teaches column 2 lines 45-47, "As the bladders inflate and deflate in sequence, the pressure on the skin in different locations will cause the muscle to be massaged to increase blood circulation." The prior art teaches the motivation for using the inflatable bladders within a cast. It is not clear how applicant can disregard this teaching.

19. Regarding Corcoran, Corcoran teaches that these inflatable bladders can be used on any extremity to improve the venous flow. No one body extremity has the monopoly on the need for improving venous flow. While Taheri may show an embodiment for just the lower legs, Corcoran teaches that the lower arm also needs the same help. Corcoran teaches both.

20. Regarding Johnson and claim 36, it is not clear how applicant can disregard the teaching of Johnson. Johnson is another wrap for a limb extremity for improving venous flow where the outer shell is taught to be rigid. Exemplifies again to the applicant that providing inflexibility of the outer shell is well known to the artisan of ordinary skill. It is not clear how applicant can repeatedly ignore the teaching of the prior art.

21. Clearly, the examiner's use of "clearly" is very clear.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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